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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,047	04/15/2004	Steven Odrich	2755.025US1	7403

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Pillsbury Winthrop Shaw Pittman LLP (QLT)
P.O. Box 10500
McLean, VA 22102

EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
04/08/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,047	ODRICH ET AL.	
	Examiner	Art Unit	
	NISSA WESTERBERG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,13-19,21,23-33 and 35-41* is/are pending in the application.

4a) Of the above claim(s) *13,16,18,19,23-28,32,35 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,14,15,17,21,29-31,33 and 37-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 21, 2010 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 11, 15, 17, 21, 29 – 31, 33, and 37 were rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (US 3,949,750). This rejection is MAINTAINED for the reasons set forth below.

Freeman discloses a punctal plug with a proximal and distal end by using the plug as a means to prevent drainage of lacrimal fluid from the eye or as a carrier vehicle

for storing and delivering medication to eye (col 1, ln 8 – 14). The plug is impregnated with or otherwise acts as a carrier material for an ophthalmic medication (abstract). As can be seen in figures, particularly figures 2A and 2B, the plug can have a head region (part 28 or 28'), which reads on an outer stopper structure, and a lower portion (part 22 or 22') which is an inner stopper structure as recited in claim 33. In certain embodiments, the plugs (part 20 or 20'), particularly the head portion can be made of a porous material or otherwise configured to store and slowly dispense ophthalmic drugs to the eye as they are leached out by the lacrimal fluids (col 5, ln 8 – 14 and claim 4). The plus is made of tissue tolerable, readily sterilizable inert materials (claim 3). Thus, Freeman discloses a punctal plug in which the body is made of a porous material impregnated with drug that provides a sustained release of the active ingredient from the plug. This includes the proximal end that will release active agent from the exterior surface. The exact time course of release is not disclosed but the delivery of active ingredient over time is disclosed. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Applicants traverse this rejection on the grounds that impregnating a material with drug does not necessarily saturate the material with drug. As this must necessarily

be present in order for a reference to anticipate, the present claims are patentably distinct.

This argument is unpersuasive. Attached to this office action is the "impregnate" entry from dictionary.com (accessed April 6, 2011). Multiple definitions of this term indicate that impregnate means saturated (definition 3, p 2; definition 1, p 4; and two definitions on p 5 including definition 2 from the medical dictionary). Also note definition 4 on page 2, which indicates that impregnate means "to fill interstices with a substance". While the instant claims and the applied prior art may not use the same terminology, this definition provides the requested evidence that the drug impregnated punctal plugs of Freeman anticipates the instant claims that require saturation of the drug in the punctal plug.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 11, 15, 17, 21, 30, 31, 34, 37 and 41 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ness (US 3,828,777). This rejection is MAINTAINED for the reasons set forth below.

Figure 4 discloses an ocular insert according to Ness (col 8, ln 19 - 33). The device is comprised of a body of microporous drug release rate controlling matrix material (**40**) having drug (**41**) dispersed throughout. Part **41** functions as both the reservoir and the release rate controlling mechanism to continuously dispense a metered amount of drug to the eye and tissue over a prolonged period of time (col 8, ln 23 - 28). This includes the proximal end that will release active agent from the exterior surface. The drug is a medicine and the antibiotics or sulfonamides (col 8, ln 56 – 67) read on medication for treatment of an eye. The physical dimensions for the device are

4 to 20 mm in length, 1 to 12 millimeters in width and 0.1 to 2 mm in thickness (col 7, ln 38 – 40). The materials that make up the implant (the drug release rate controlling materials) are biological compatible with the physical environment of the eye and insoluble (col 4, ln 56 – 65) and at least some of the various materials listed, such as polydimethylsiloxane (col 11, ln 65) are inert.

Ness does not explicitly describe a prolonged release time period of active ingredient of 3-6 months or explicitly described an implant dimensioned to be implanted in the lacrimal punctum.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to prepare an ocular device with a 3 – 6 month period of drug release. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Ness discloses that the insert provides prolonged release over a prolonged period of time and that devices containing different amounts of drug for use for different time periods and releasing drug at higher or lower ate are also readily made by the invention (col 8,lnm 34 – 55). The length of time for drug release from the insert is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal length of time for drug release based on the particular active agent selected, the dose of the active ingredient to be delivered and how frequently the patient will require treatment and/or

time between insertion of a new ocular insert. Longer duration of drug release will require the presence of more drug in the implant and the maximal amount of drug that can be contained in the device will be obtained when the device is saturated with drug.

It also would be obvious to optimize the size of the implant. Devices at the lower end of the size ranges disclosed by Ness are sized for insertion in the lacrimal punctum of a subject. "Punctal plug" indicates the intended use location of the composition being claimed. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While the devices of Ness are disclosed for use in sac of the eye, the devices at the lower end of the size ranges disclosed by Ness are capable of being inserted into the lacrimal punctum.

8. Claims 14, 29, 33, 38, 40, 42 and 44 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ness as applied to claims 11, 15, 17, 21, 30, 31, 37 and 41 above, and further in view of Cohan et al. (US 6,196,993). This rejection is MAINTAINED for the reasons set forth herein.

As described in greater detail above, Ness discloses an ocular implant made entirely from a porous or absorbent material and active agent that provides for the prolonged release of active agent to the eye. The devices can be of a size that is capable of being inserted in a lacrimal punctum.

Ness does not disclose the inclusion of latanoprost as a drug, an outer stopper structure or an inner stopper structure.

Cohan et al. discloses ophthalmic inserts for the sustained release of medication to the eye comprising a body portion sized to pass through a lacrimal punctum with a collarete structure that sits on the exterior or the lacrimal punctum (abstract). Units designed to be placed in conjunctival cul-de-sac such as those disclosed by Ness (US 3,626,340) are uncomfortable due to their positioning, leading to poor patient acceptance (col 2, ln 8 – 20). That collarete forms an outer stopper structure configured to seat against the lacrimal punctum. Part 38 can be included and shown in figure 3 to help secure the insert within the canaliculus (col 4, ln 45 – 48), raeding on an inner stopper structure. Anti-glaucoma drugs such as latanoprost can be administered using an ocular implant that releases drug over a sustained period of time (col 7, ln 5 – 8).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate medication for the treatment of glaucoma such as latanoprost in the ocular insert of Ness. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Cohan et al. discloses that latanoprost is a drug suitable for sustained administration to the eye by implantation of a drug releasing implant.

It also would obvious to include an outer stopper structure to prevent the device from being inserted too deeply and/or an inner stopper structure to aid in holding the device in place inside the canaliculus as taught by Cohan et al.

Applicant traverses this rejection on the grounds that Cohan does not recite the features recited in claim 11.

These arguments are unpersuasive. As discussed above, the possible dimensions of the ocular implant taught by Ness make an ocular implant capable of being used a punctal plug. Cohan explicitly references the devices of Ness as being uncomfortable, which leads to poor patient compliance. The solution is the forming of a punctal plug. It would be also be obvious to modify the implant of Ness to be a punctal plug to provide drug delivery without the discomfort. While the drug release configuration of the devices in Ness and Cohan are different, they are analogous art as they are both in the same field of endeavor – ocular implants that release drug over a prolonged period of time the tissue of an eye and/or nasolacrimal system. The drug implant of Ness can be altered in shape slightly to form a punctal plug and will not require making a punctal plug with a reservoir as the drug is stored throughout the entire body of the plug.

9. Claims 39 and 43 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ness in view of Cohan et al. as applied to claims 11, 14, 15, 17, 21, 29 – 31, 33, 34, 37, 38, 40 – 42 and 44 above, and further in view of Robertson (US 2002/0193441). This rejection is MAINTAINED for the reasons set forth herein.

As discussed in greater detail above, Ness and Cohan disclose a punctal plug to dispense a glaucoma medication such as latanoprost over a prolonged period of time.

The inclusion of inner and/or outer stoppers aids in proper localization of the device and retention of the punctal plug ocular implant in that position.

Neither reference discloses travoprost or bimatoprost as medication for the treatment of glaucoma.

Robertson discloses that latanoprost, travoprost and bimatoprost are prostaglandin analogs that reduces intraocular pressure and treats glaucoma (¶ [0011]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate travoprost or bimatoprost as the anti-glaucoma active agent in the ocular implant taught by Ness and Cohan et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Robertson teaches that the glaucoma medication latanoprost taught by Cohan et al. is functionally equivalent to travoprost and bimatoprost, which are also prostaglandin analogs useful in the treatment of glaucoma.

Applicant traverses this rejection on the grounds that Robertson does not remedy the deficiencies of Ness and Cohan.

This argument is unpersuasive. As discussed in greater detail above, Ness and Cohan are not deficient so Robertson is not required to cure the alleged deficiencies.

10. Claims 45 and 46 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ness, optionally in view of Cohan et al., further in view of Yanni et al. (WO 00/03705). This rejection is MAINTAINED for the reasons set forth herein.

As described in greater detail above, Ness discloses an ocular implant made entirely from a porous or absorbent material and active agent that provides for the prolonged release of active agent to the eye. Cohan teaches a drug releasing punctal plug that relieves the discomfort associated with use of drug delivery devices such as those taught by Ness.

Ness does not disclose olopatadine as a drug which can be delivered using the implant.

Yanni et al. discloses that 11-(3-dimethylaminopropylidene-6,11-dihydrodibenzyl[b,e]oxepin-2-acetic acid, also known as olopatadine, can treat or prevent ophthalmic neovascularization and non-allergic inflammatory disorders involving cytokine release from human ocular cells by administering an ophthalmic formulation of olopatadine (p 3, ln 3 – 8). It can be administered to the eye via an implant (p 4, ln 9).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use to administer olopatadine from the drug delivery device of Ness. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Yanni et al. discloses that olopatadine can be administered to the eye via implant for the treatment of ophthalmic neovascularization and non-allergic inflammatory disorders involving cytokine release. The materials that make up the implant will provide sustain release of the active agent (e.g., olopatadine) to tissue at or near one or both of any eye or a nasolacrimal system.

11. Claims 11, 15, 17, 21, 29 – 31, 33, 37 and 41 were rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (US 3,949,750) in view of Bhushan (US 2004/0137068). This rejection is MAINTAINED for the reasons set forth herein.

Freeman discloses a punctal plug with a proximal and distal end by using the plug as a means to prevent drainage of lacrimal fluid from the eye or as a carrier vehicle for storing and delivering medication to eye (col 1, ln 8 – 14). The plug is impregnated with or otherwise acts as a carrier material for an ophthalmic medication (abstract). As can be seen in figures, particularly figures 2A and 2B, the plug can have a head region (part 28 or 28'), which reads on an outer stopper structure, and a lower portion (part 22 or 22') which is an inner stopper structure as recited in claim 33. In certain embodiments, the plugs (part 20 or 20'), particularly the head portion can be made of a porous material or otherwise configured to store and slowly dispense ophthalmic drugs to the eye as they are leached out by the lacrimal fluids (col 5, ln 8 – 14 and claim 4). The plus is made of tissue tolerable, readily sterilizable inert materials (claim 3). Thus, Freeman discloses a punctual plug in which the body is made of a porous material impregnated with drug that provides a sustained release of the active ingredient from the plug. This includes the proximal end that will release active agent from the exterior surface.

Freeman does not explicitly disclose the length of time over which drug delivery takes place.

Bhushan discloses an ophthalmic formulation for treatment of ocular conditions such as age-related macular degeneration (abstract). These formulations are administered multiple times a day for a time period of more than 1 year (¶ [0082]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a punctal plug releasing an ophthalmic active ingredient over time, to prepare such a plug so that the drug is released over a time period of many months, a time frame of treatment that is employed in the treatment of ocular conditions by administration of a formulation directly to the eye, as taught by Bhushan. Longer duration of drug release will require the presence of more drug in the implant and the maximal amount of drug that can be contained in the device will be obtained when the device is saturated with drug.

Applicants traverse this rejection on the grounds that Bhushan does not make up for the deficiencies of Freeman discussed above.

This argument is unpersuasive. As discussed in greater detail above in the 102 section, Freeman is not deficient as alleged by Applicant so Bhushan is not required to cure those alleged deficiencies.

12. Claims 11, 15, 17, 21, 29 – 31, 33, 37, 38, 40, 42 and 44 were rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Cohan et al. (US 6,196,993). This rejection is MAINTAINED for the reasons set forth herein.

Freeman discloses a punctal plug with a proximal and distal end by using the plug as a means to prevent drainage of lacrimal fluid from the eye or as a carrier vehicle

for storing and delivering medication to eye (col 1, ln 8 – 14). The plug is impregnated with or otherwise acts as a carrier material for an ophthalmic medication (abstract). As can be seen in figures, particularly figures 2A and 2B, the plug can have a head region (part 28 or 28'), which reads on an outer stopper structure, and a lower portion (part 22 or 22') which is an inner stopper structure as recited in claim 33. In certain embodiments, the plugs (part 20 or 20'), particularly the head portion can be made of a porous material or otherwise configured to store and slowly dispense ophthalmic drugs to the eye as they are leached out by the lacrimal fluids (col 5, ln 8 – 14 and claim 4). The plus is made of tissue tolerable, readily sterilizable inert materials (claim 3). Thus, Freeman discloses a punctual plug in which the body is made of a porous material impregnated with drug that provides a sustained release of the active ingredient from the plug. This includes the proximal end that will release active agent from the exterior surface.

Freeman does not explicitly disclose a prostaglandin derivative such as latanoprost as an active agent suitable for delivery by the punctal plug,

Cohan et al. discloses that latanoprost is an anti-glaucoma drug that can be delivered by means of punctal plug device which releases the active agent onto the eye (col 7, ln 4 – 10; abstract)

It would have been obvious to one ordinary skill in the art at the time of the instant to prepare a punctal plug as taught by Freeman and to use latanoprost as the active ingredient. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because

Cohan et al. teaches that latanoprost is an anti-glaucoma agent suitable for direct administration to the eye.

Applicant traverses this rejection on the grounds that any reasonable combination of Freeman and Cohan does not teach all of the limitations of independent claims 11 and 30.

This argument is unpersuasive. As discussed in greater detail above in the 102 section, Freeman teaches all the limitations of claims 11 and 30. As Freeman is not deficient as alleged by Applicant, Cohan is not required to cure those deficiencies.

13. Claims 39, 41 and 43 were rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Cohan as applied to claims 11, 15, 17, 21, 29 – 31, 33, 37, 38, 40, 42 and 44 above, and further in view of Robertson (US 2002/0193441). This rejection is MAINTAINED for the reasons set forth herein.

Freeman discloses a punctal plug in which the body discharges medication from an exterior surface portion of the distal end of the plug body (col 5, ln 8 – 14) and provides a sustained release of the active ingredient from the plug. A variety of active agents, including anti-glaucoma agents such as latanoprost as taught by Cohen et al. (col 7, ln 4 – 10) can be administered using such ocular implants.

Neither reference discloses travoprost or bimatoprost as medication for the treatment of glaucoma.

Robertson discloses that latanoprost, travoprost and bimatoprost are prostaglandin analogs that reduces intraocular pressure and treats glaucoma (¶ [0011]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate travoprost or bimatoprost as the active agent in the ocular implant taught by Freeman, devices which can be used to deliver medications for the treatment of glaucoma as taught by Cohan et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Robertson teaches that the glaucoma medication latanoprost taught by Cohan et al. is functionally equivalent to travoprost and bimatoprost, which are also prostaglandin analogs useful in the treatment of glaucoma.

Applicant traverses this rejection on the grounds that Robertson does not remedy the deficiencies of Freeman and Cohan.

This argument is unpersuasive. As discussed in greater detail above, Freeman and Cohan are not deficient so Robertson is not required to cure the alleged deficiencies.

14. Claims 11, 15, 17, 21, 29 – 31, 33, 37, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Yanni (WO 00/03705). This rejection is MAINTAINED for the reasons set forth herein.

Freeman discloses a punctal plug with a proximal and distal end by using the plug as a means to prevent drainage of lacrimal fluid from the eye or as a carrier vehicle for storing and delivering medication to eye (col 1, ln 8 – 14). The plug is impregnated with or otherwise acts as a carrier material for an ophthalmic medication (abstract). As can be seen in figures, particularly figures 2A and 2B, the plug can have a head region

(part 28 or 28'), which reads on an outer stopper structure, and a lower portion (part 22 or 22') which is an inner stopper structure as recited in claim 33. In certain embodiments, the plugs (part 20 or 20'), particularly the head portion can be made of a porous material or otherwise configured to store and slowly dispense ophthalmic drugs to the eye as they are leached out by the lacrimal fluids (col 5, ln 8 – 14 and claim 4). The plus is made of tissue tolerable, readily sterilizable inert materials (claim 3). Thus, Freeman discloses a punctual plug in which the body is made of a porous material impregnated with drug that provides a sustained release of the active ingredient from the plug. This includes the proximal end that will release active agent from the exterior surface.

Freeman does not disclose olopatadine as an active agent that can be delivered using the punctal plug.

Yanni et a. discloses that 11-(3-dimethylaminopropylidene-6,11-dihydrodibenzyl[b,e]oxepin-2-acetic acid, also known as olopatadine, can treat or prevent ophthalmic neovascularization and non-allergic inflammatory disorders involving cytokine release from human ocular cells by administering an ophthalmic formulation of olopatadine (p 3, ln 3 – 8). It can be administered to the eye via an implant (p 4, ln 9).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the implant of Freeman to administer olopatadine. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Yanni et al. discloses that olopatadine can be administered to the eye via implant for the treatment

of ophthalmic neovascularization and non-allergic inflammatory disorders involving cytokine release and would provide prolonged release to the eye from the implant with without daily application by the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NISSA WESTERBERG whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nissa M Westerberg/
Examiner, Art Unit 1618